Theme 5: Improving Quality of Care and Performance Under CMS Programs

Summary: Quality is a key theme in future health systems change. In recent years, there has been a growing public awareness of medical errors and issues with quality of care. Studies have pointed out that, although our health system provides some of the most advanced, high-quality medical treatments, there are variations in quality of care and areas for improvement. Health care providers have played a major role in initiating quality improvement efforts. Over the years, some purchasers have collaborated with providers to promote quality improvement, especially by distributing information to providers and health plans regarding performance. CMS's research program continues to pursue efforts to develop better information about health care quality for patients, caregivers, and providers; develop new measures of quality; and create incentives for providers to improve quality.

Development and Production of the Medicare Quality Monitoring System

Project No: 500-95-0058/16

Project Officer: Benedicta Abel-Steinberg September, 2000 to July, 2003

Funding: \$1,173,065

Principal

Investigator: Nancy McCall Award: Task Order

Awardee: Research Triangle Institute

411 Waverley Oaks Road, Suite 330

Waltham, MA 02452-8414

Description: The CMS Medicare Quality Monitoring System (MOMS) tracks various aspects of the health status and health care of the Medicare beneficiaries using a combination of survey and administrative data. The primary goal of the MQMS is to collect, analyze, and interpret national and/or State-specific health data (both surveys and administrative data) on service utilization. health status, and outcomes on morbidity and mortality relevant to CMS's Health Care Quality Improvement Project (HCOIP). The secondary goal is to disseminate the health and quality-of-care data/information to support quality-of-care improvement efforts and to promote HCQIP-related studies. Specifically, this effort produces two sets of data and information. One exhibits the trends, patterns, and variations of service utilization and health status of Medicare beneficiaries, while the other exhibits the trends, patterns, and variations of specific health outcomes relevant to HCQIP. HCQIP initially focused on acute myocardial infarction (AMI), however, CMS expanded its national quality improvement activities and is focusing on six clinical priority areas: AMI, breast cancer, diabetes, heart failure, pneumonia, and stroke. The objective of the national quality improvement activity is to reduce health disparities within the Medicare population.

The MQMS will provide the information essential for CMS to account for the effectiveness of the HCQIP efforts in changing the patterns of service utilization and in improving the health, morbidity, and mortality of the Medicare beneficiaries. The MQMS is designed to fully address issues of disease-specific health status and outcomes of care at the State level, and is relevant to program improvement and accountability of the HCQIP.

Status: The MQMS project team has presented the project to the Information Technology Project Review and Coordination Panel and an Integrated Project Team has been assigned by the panel to support the project throughout the system development life cycle. The MQMS project team has assembled an Internal Technical Workgroup to assist the development and production of the MQMS. Measures for service utilization, process, and outcomes of care are finalized, and data specifications for the measures are under development. The conceptual framework for health status is drafted. The contractor has obtained access to the HCFA mainframe and has initiated the task of extracting claims data (Parts A and B) and enrollment data (denominator files) of calendar years 1992–1999 through the Decision Support Access Facility. An expert panel on the contents and presentations of the MQMS reports is assembled, and a meeting with the expert panel is scheduled.



Design and Implementation of Medicare Home Health Quality Assurance Demonstration

Project No: 500-94-0054
Project Officer: Armen Thoumaian
September, 1994 to
December, 2003

Funding: \$5,185,699

Principal

Investigator: Peter Shaughnessy

Award: Contract

Awardee: Center for Health Services

Research

University of Colorado

1355 South Colorado Boulevard

Suite 706

Denver, CO 80222

Description: The Medicare Home Health Quality Assurance Demonstration has developed and tested an approach to develop outcome-oriented quality assurance techniques and promote continuous quality improvement in home health agencies (HHA). The goal of the demonstration was to determine the feasibility of a methodology for a national approach for outcomebased quality improvement (OBQI). Outcome measures were computed using the Outcomes and Assessment Information Set (OASIS). Under the demonstration, staff of 54 regionally dispersed HHAs completed the OASIS data collection instrument for each patient at the start of care and at 60-day intervals (up to and including discharge). The Center for Health Services Research then conducted three rounds of data analysis and outcome report generation, each based on 12 months of data. Risk-adjusted reports are produced for 41 specific patient quality outcomes for all adult patients. These reports are provided to the participating HHAs and are used to determine which outcomes need improvement, thereby providing a focus for agency staff to target problematic care. The demonstration resulted in significant improvement in 80 percent of agency-specific outcome targets, with a yearly improvement in re-hospitalization rates across all agencies.

Status: Fifty-four agencies in twenty-six States were phased into the demonstration beginning in January 1996. Beginning in January 1997, the demonstration agencies received their first outcome reports and developed plans of action to improve care for two patient outcomes during 1997. Agencies received their second annual reports in May 1998, which contained baseline comparisons from 1997, and received their third and final reports in May 1999. A final report has been completed and is available. Funding was increased to a total of \$5,185,000 and the project was extended 3 years to 12/31/03. Following completion of the demonstration project, the contract was modified to provide technical and data analysis and consultative support to CMS to implement nationwide OASIS through the Center for

Medicaid and State Operations, to develop the OBQI system for subsequent national implementation through the Quality Improvement Organization program of the Office of Clinical Standards and Quality, perform research on new risk adjustment methodologies, develop the OASIS/OBQI Change and Evolution Program, and provide OASIS/OBQI-related technical analysis and consultation support to CMS and its components. This contract ends December 31, 2003. Many of the activities begun under this contract will be continued under the OASIS Technical Analysis and Support Contract. ■

Development of Quality Indicators for Inpatient Rehabilitation Facilities

Project No: 500-00-0024/04

Project Officers: Pauline Karikari-Martin and

Rita Shapiro

Period: September, 2001 to

September, 2004

Funding: \$1,420,000

Principal

Investigator: Shulamit Bernard Award: Task Order

Awardee: Research Triangle Institute (NC)

3040 Cornwallis Road PO Box 12194

Research Triangle Park, NC

27709-2194

Description: The purpose of this project is to support developing and defining measures to monitor the quality of care and services provided to Medicare beneficiaries receiving care in inpatient rehabilitation facilities. It will identify the elements integral to assessing quality of care in rehabilitative services and developing a set of measures for use by States.

Status: This project is in its deliverable stages. A second technical evaluation panel occurred in November 2003.

Premier Hospital Quality Incentive Demonstration

Project No: 95-W-00103/04 **Project Officer:** Katharine Pirotte

Period: October, 2003 to October, 2006

Funding: \$32,000,000

Principal

Investigator: Gretta Hill Award: Contract

Awardee: Premier Healthcare Informatics

2320 Cascade Pointe Boulevard

Suite 100

Charlotte, NC 28266-8800

Description: The purpose of the demonstration is to determine the effectiveness of economic incentives



targeted toward improving the quality of inpatient care for Medicare beneficiaries by giving financial incentives to hospitals for high quality and by reporting quality data on the CMS Web site.

Status: The demonstration began on 10/1/03. Premier, Inc., is a very large association of nonprofit hospitals. It operates a quality measurement organization for about 500 hospitals. The demonstration project includes about 287 of the 500 Premier hospitals.

Evaluation of Group-Specific Volume Performance Standards Demonstration

500-95-0048/04 **Project No: Project Officer:** John Pilotte

Period: September, 1996 to

September, 2002

Funding: \$2,220,440

Principal

Investigator: Janet Mitchell Award: Task Order

Awardee: Research Triangle Institute

411 Waverley Oaks Road, Suite 330

Waltham, MA 02452-8414

Description: The purpose of this task order is to comprehensively evaluate the Group-Specific Volume Performance Standards Demonstration. Additionally, there is a group of tasks to provide technical support for setting sites' targets and measuring their actual performance. The goal of the demonstration is to test the feasibility of this partial-risk-bearing payment arrangement between CMS and qualifying physicianbased organizations in the fee-for-service (FFS) market, whereby FFS rules apply within the context of a performance target, beneficiaries are not enrolled, and physician-sponsored organizations develop structures and processes to manage the services and cost of care received by FFS patients.

Status: In developing the final design parameters of the GVPS demonstration, simulations were conducted to analyze low and high expenditure outliers, eligibility mix changes, components of growth rates by type of service, and effects of case-mix adjustments. These analyses reveal sources of variability in growth rates and support development of options for setting targets and calculating updates and bonus payments. The evaluator is awaiting the initiation of the demonstration.

Evaluation of Physician Group Practice Demonstration

Project No: 500-00-0024/12 **Project Officer: John Pilotte**

Period: September, 2003 to May, 2004

\$2,900,000 **Funding:**

Principal

Award:

Investigator: **Gregory Pope** Task Order

Research Triangle Institute (NC) Awardee:

3040 Cornwallis Road

PO Box 12194

Research Triangle Park, NC

27709-2194

Description: Physicians influence, either directly or indirectly, almost all areas of Medicare spending. For example, physicians deliver services, admit beneficiaries to hospitals, and authorize home health visits. The Physician Group Practice (PGP) demonstration will enable us to test physician groups' response to financial incentives for improving care coordination, delivery processes, and patient outcomes, and the effect on access, cost, and quality of care to Medicare beneficiaries.

The PGP Demonstration seeks to align incentives for physician groups to manage the overall care of its patients. The demonstration encourages health care groups to attract, retain, and coordinate care to beneficiaries; gives physicians incentives to provide services efficiently to their patients; provides a framework in which we can collaborate with providers to the advantage of Medicare beneficiaries; and promotes active use of utilization and clinical data for the purpose of improving efficiency and outcomes.

Status: This project is in the start-up phase.

Implementation of Quality Improvement **Organization Sixth Scope of Work Pneumococcal** Pneumonia and Influenza Immunization Remeasurement Survey

500-95-0062/11 **Project No: Project Officer:** Susan Arday Period: September, 2000 to September, 2003

\$1,542,230

Funding:

Principal

Investigators: Pamela Giambo and Skip Camp

Award: Task Order Abt Associates, Inc. Awardee:

55 Wheeler Street Cambridge, MA 02138



Description: The goal of this project is to assess the utilization of influenza and pneumococcal vaccines among Medicare beneficiaries and to evaluate the vaccine promotion work performed by Peer Review Organizations (PROs) under their Medicare Sixth Scope of Work. The PROs are charged to decrease morbidity and mortality in six national clinical priority areas, one of which is pneumonia and influenza. This project specifically implements the Pneumococcal Pneumonia and Influenza Immunization Remeasurement Survey. The survey is administered to a sample of Medicare beneficiaries randomly selected from each of 50 States, plus the District of Columbia and Puerto Rico. It will also produce the attendant State-specific rates. Baseline rates for outpatient elderly Medicare beneficiaries' influenza and pneumococcal pneumonia immunizations have been obtained from the Centers for Disease Control and Prevention's (CDC) 1999 administration of the Behavioral Risk Factor Surveillance System (BRFSS). However, the BRFSS cannot be used by the PROs for remeasurement because of mismatches between the PROs' timetable for evaluation and that of subsequent BRFSS survey administrations and data release from those administrations.

Status: The project is completed.

Clinical and Economic Effectiveness of a Technology-Driven Heart Failure Monitoring System

Project No: 18-C-91172/03
Project Officer: John Pilotte
September, 2000 to
September, 2004

Funding: \$3,000,000

Principal

Investigator: Mariell Jessup, M.D.

Award: Cooperative Agreement

University of Pennsylvania
Heart Failure and Cardiac

Transplant Program 6 Penn Tower 3400 Spruce Street Philadelphia, PA 19104

Description: This demonstration project assesses the impact of the Alere DayLink Heart Failure Monitoring System on the clinical outcome and economic effect among Medicare beneficiaries recently hospitalized for heart failure or acute exacerbation of previously existing heart failure. The project first looks at the addition of the Alere DayLink Heart Failure Monitoring System to standard management of heart failure medical care impact on re-hospitalizations for heart failure over 6 months. Second, the project will analyze the impact of the monitoring system on utilization of other Medicare services, Medicare costs, functional status, processes of

care, physician adherence to recommended clinical care guidelines, patient adherence with prescribed therapy, social support, and patient acceptance and satisfaction. Patients initially randomized to this technology will be re-randomized to either an additional 6 months of monitoring or to standard heart failure medical care with discontinuation of the Alere telemonitoring to assess the persistence of the intervention's effectiveness. Third, analysis will explore the impact of the extended 6 months of this monitoring system on re-hospitalization rates for heart failure, utilization of Medicare services, Medicare costs, patient adherence to the prescribed medical regimen, and functional status. Thus, the demonstration will assess the impact of this technology on a range of clinically and policy relevant heart failure outcomes. Four hundred-forty Medicare beneficiaries recently hospitalized for management of new onset heart failure or for an acute exacerbation of previously existing heart failure will be enrolled at three geographical sites of different character: "rural"—Billings, Montana; "small Metropolitan Statistical Area"—Louisville, Kentucky; and "major Metropolitan Statistical Area"— Philadelphia, Pennsylvania.

Status: The site began enrollment in 2001 and has enrolled more than 300 patients. ■

Develop, Conduct, and Analyze Surveys of Providers That Work With Quality Improvement Organizations (QIO)

Project No: 500-01-0020/01 **Project Officer:** Mei Wang

Period: September, 2002 to March, 2005

Funding: \$782,194

Principal

Investigator: William Taylor, M.D.

Award: Task Order

Awardee: Westat Corporation

1650 Research Boulevard Rockville, MD 20850

Description: The purpose of this project is to collect information on the satisfaction of health care providers with the performance of the Quality Improvement Organizations (QIOs). The survey results will be combined with performance measures to evaluate the results of the QIOs in the seventh scope of work. To gain a broad view of the quality of the QIOs' interactions, we sampled providers from nursing homes, home health agencies, hospitals, physician offices, and managed care organizations. The sample size is 20,000 providers, to ensure an adequate sample to make comparisons across provider settings and the States. The questionnaire was developed to measure satisfaction across several domains, and a composite measure was designed for the evaluation. The survey is a mailed questionnaire with an option of using the Web to enter responses. Telephone



interviews will be conducted for those who do not respond. The final report from these surveys will be completed by March 2005.

Status: The surveys are beginning and will require 9 months of field work to complete because of the staggered contract starting dates. The final report will be completed by March 2005. ■

Developing and Evaluating the Use of a Quality Indicator Format in the End Stage Renal Disease Survey Process

Project No: 500-96-0005/04
Project Officer: Judith Kari

Period: September, 1999 to June, 2003

Funding: \$466,231

Principal

Investigator: Robert Rubin
Award: Task Order
Awardee: Lewin Group

3130 Fairview Park Drive, Suite 800

Falls Church, VA 22042

Description: The purpose of this project is to develop, test, and describe improved processes and formats for enhancing the survey process for End Stage Renal Disease (ESRD) facilities. An improved survey process would include effectively using quality indicators in the survey process, developing more consistent and accurate survey results, and developing more efficient and objective ways to record survey results. The Balanced Budget Act of 1997 (BBA) directs the Secretary of Health and Human Services to develop and implement a method to measure and report quality of renal dialysis services provided under the Medicare program under Title XVIII of the Social Security Act. CMS has been assigned the responsibility for the development and implementation of this area of the BBA.

As the ability to measure quality of care and patient outcomes in ESRD has improved, we are interested in translating this knowledge base into facility-specific indicators that inform and support the current survey and certification process. One of the areas that we are interested in enhancing is the ability to use quality indicators in the survey process. We also are interested in developing more consistent and accurate survey results and enhancing the efficiency and objectivity of recording data and information collected during the survey process. As a response to the BBA, CMS emphasized its support for a data-driven ESRD survey system. In an effort to provide a data-driven survey system, CMS felt that it was necessary to develop and utilize facility-specific data reports for the survey process. In 1998, we used a

professional review organization (PRO) to facilitate the development of a facility-specific data report for State surveyors. As a part of this project, the PRO produced a format of a facility-specific data report for CMS at the end of 1999. The data report will be pilot tested with nine States during the first quarter of 2000. After receiving feedback from the pilot test States, the report will be modified with the most current year's data. In September 2000, the PRO will provide training to State surveyors from all 50 States and release the report to the States. It is anticipated that the availability of the facility-specific data reports will change the ESRD survey process. The data reports will provide quality indicators for focusing the survey process and descriptive elements for informing the process.

In addition to having these facility-specific reports available for the survey process, we would like to enhance the consistency and accuracy of the survey process. Specifically, we would like to find more efficient and objective ways to record and report survey results.

Status: The progress on this project has been suspended since February 2000. ■

Evaluating the Use of Quality Indicators in the Long-Term Care Survey Process

Project No: 500-96-0010/03 **Project Officer:** Karen Schoeneman

Period: September, 1998 to February, 2004

Funding: \$3,934,228

Principal

Investigator: Angela Greene Award: Task Order

Awardee: Research Triangle Institute (NC)

3040 Cornwallis Road

PO Box 12194

Research Triangle Park, NC

27709-2194

Description: This project will evaluate how to integrate quality indicators into the regulatory process. Quality indicators could be used for monitoring and assessing facility performance in numerous domains and supporting appropriate corrective and enforcement actions. This task order will develop and test various options for using a variety of quality indicators to improve the effectiveness and efficiency of CMS's monitoring of facility performance.

Status: Development and incorporation of successful beta testing of the completed system continued through 2003. ■



Evaluation of Independent Informal Dispute Resolution (IDR) Process

Project No: 500-97-0440/18
Project Officer: Elaine Lew

Period: September, 2000 to

September, 2003

Funding: \$973,052

Principal

Investigator: Barbara Holt Award: Task Order

Awardee: Kathpal Technologies

2230 Gallows Road, Suite 380

PO Box 705

Dunn Loring, VA 22027

Description: The project evaluates the effectiveness of the current and independent informal dispute resolution (IDR) process in order to ascertain whether revisions should be made to the nursing home certification program. The current process gives a nursing home the opportunity to informally dispute survey findings to the State Survey Agency following the receipt of the Statement of Deficiencies. However, since the individuals who approve of the survey findings are sometimes the same ones who review IDR cases, the process is often viewed as not objective. This project responds to a recommendation in a Congressional Appropriations Committee Report (FY 2000) for CMS to initiate a pilot study using an independent entity to conduct the nursing home IDR process.

Status: Two States (Iowa and Texas) have participated in CMS's independent IDR pilot study. For the duration of the study, these States replaced their current IDR process with an IDR process conducted by an entity outside of the State Survey Agency. The contractor has collected information from the two pilot States to establish baseline data from which to compare and have met with staff from the State Survey Agencies, as well as the State provider organizations and advocates, to capture their perceptions of the current IDR process. ■

Improving Nursing Home Enforcement

Project No: 500-00-0035/02
Project Officer: Elaine Lew
Period: September, 2001 to

September, 2004

Funding: \$763,580

Principal

Investigators: Linda Clark-Helms and

Steven Garfinkel

Award: Task Order

Awardee: C.N.A. Corporation 4401 Ford Avenue

PO Box 16268

Alexandria, VA 22302-8268

Description: This purpose of this project is to assess the effectiveness of enforcement as the primary public policy for ensuring nursing home quality and protecting residents. This study will assess the overall effectiveness of the survey and certification regulatory system and identify specific policy issues and options for improvement.

Status: Case studies are being conducted in two States to examine whether the delivery of care in nursing homes is affected by survey and enforcement actions. Also, through separate prospective case studies, this project is examining whether the informal dispute resolution process is meeting the intent of the 1995 survey and enforcement regulations.

Improving Nursing Home Enforcement—Phase 2

Project No: 500-00-0026/03
Project Officer: Marvin Feuerberg
September, 2003 to September, 2005

\$693,963

Funding: Principal

Investigator: David West **Award:** Task Order

Awardee: University of Colorado Health

Sciences Center

1355 South Colorado Boulevard

Suite 706

Denver, CO 80222

Description: The basic purpose of this contract is to assess the effectiveness of the current system of enforcement. Some aspects of this system of survey and certification have been the subject of GAO and OIG investigations (e.g., CMS oversight of State Survey Agencies) or other related CMS projects. These areas will not be addressed in this contract, although the relevant findings will be incorporated into a comprehensive final report required of this project. There are, however, other specific enforcement processes that have not been the subject of investigation. In addition, there are fundamental assumptions of the enforcement system that have never been subject to empirical testing. Hence, the purpose of this contract is to do the following:

- Conduct a study on these previously unstudied aspects of enforcement
- Evaluate the overall effectiveness of the system
- Identify policy issues and options for improvement

This contract assesses the overall effectiveness of the current system quantitatively through a retrospective analysis of the impact of enforcement on resident outcomes. Overall effectiveness is also assessed qualitatively through prospective case studies on the



impact of enforcement on provider care processes. In addition, a number of issues related to survey agencies' response to complaints are examined with the objective of generating a more standardized system across States. Finally, all of the diverse empirical findings from this contract as well as other relevant investigations will be synthesized in order to identify policy issues and options for improvement.

Status: The contract was awarded in September 2003. As of January 2004, workplans and some study designs for various tasks have been generated. ■

Improving the Accuracy and Consistency of the Nursing Home Survey Project

Project No: 500-00-0032/07
Project Officer: Marvin Feuerberg
September, 2003 to

September, 2004

Funding: \$244,298

Principal

Investigator: David Kidder
Award: Task Order
Awardee: Abt Associates, Inc.
55 Wheeler Street

55 Wheeler Street Cambridge, MA 02138

Description: The purpose of this project is to assess the problem of inaccuracy and inconsistency in the survey process and systematically link that assessment to specific policy and programmatic options for improvement. Specifically, the project will have four major components:

1. Empirical Assessment of Variability and Consistency of Survey Process

This analysis will distinguish variability that is appropriate—due to real quality variations among nursing homes—from variability that is inappropriate or undesirable due to surveyor/survey agency inconsistency. Inherent in this analysis is the requirement to independently assess the real quality of care among a sample of nursing homes in order to identify inconsistent quality assessments by different survey teams/agencies. In other words, it is necessary to hold quality constant. Although the self-reported minimum data set data may have some role in this analysis, this task will require a major field work effort to collect primary data.

2. Identification of Those Aspects of Inaccuracy and Inconsistency That Are Most Troublesome

Some degree of inconsistency is to be expected of any regulatory system. Furthermore, there are many different potential sources of inconsistency. Inconsistency may be found in failure to identify real quality problems, misidentification of problems, identification of trivial as opposed to root problems, the application of scope and severity designations to identified problems, and the invoking of sanctions in response to scope and severity determinations. Furthermore, those aspects of inconsistency that are the most troublesome will reflect the interest of key stakeholders, particularly consumer advocates, providers, and survey agencies.

This analysis will survey/interview key stakeholders to determine those aspects of inaccuracy/inconsistency that are perceived as most troublesome in order to ensure that they are addressed in the project.

3. Empirical Assessment of the Most Important Causes of Inaccuracy/Inconsistency

This analysis will probably be conducted in conjunction with the first analysis listed above. Among potential causes to be examined include CMS definitions and unclear guidance; policies of individual CMS regional offices that are imposed on State survey agencies (SA); variations in SAs' interpretation of CMS policy directives, guidance, and expectations; competency/training and composition of SA teams; too many regulatory standards; political influence from State governors; the resources (e.g., cost per standard survey) directed to the survey, etc.

4. Policy and Programmatic Options for Improvement

This is at once the most difficult and most important component of the project. Not every potentially important cause can be feasibly addressed within the regulatory authority of CMS. For example, political influence from the industry through the State governor may be an important cause of inconsistency but not a factor within the purview of CMS. In contrast, survey definitions or the training of survey teams fall within CMS's current authority.

Status: The contract to Abt Associates was awarded in September 2003. As of January 2004, workplans have been generated and work is under way. ■



Improving Protocols for Home Health Agency Assessment in the Survey Process

Project No: 500-00-0026/01
Project Officers: Mavis Connolly and

Tracey Mummert

Period: September, 2001 to June, 2005

Funding: \$1,046,756

Principal

Investigator: Kathryn Crisler Award: Task Order

Awardee: Center for Health Services

Research

University of Colorado

1355 South Colorado Boulevard

Suite 706

Denver, CO 80222

Description: The purpose of this project is to assess the existing home health agency (HHA) survey process and make recommendations for improvements. Improvements include patient-focused, outcome-oriented, data-driven approaches that are effective and efficient in assessing, monitoring, and evaluating the quality of care delivered by an HHA. The project will also evaluate the effectiveness of current survey forms, develop new survey forms as applicable, and make recommendations for prioritizing onsite survey time. The assessment will focus on the Outcome and Assessment Information Set, designed for the purpose of enabling the rigorous and systematic measurement of patient home health care outcomes, with appropriate adjustment for patient risk factors affecting those outcomes; and the Online Survey Certification and Reporting System.

Status: The period of performance was extended to June 30, 2005. ■

Outcome and Assessment Information Set (OASIS) Technical Analysis and Support Contract

September, 2006

Project No: 500-00-0026/02
Project Officer: Pamela Cheetham
September, 2002 to

Funding: \$1,099,982

Principal

Investigator: Robert Schlenker **Award:** Task Order

Awardee: Center for Health Services

Research

University of Colorado

1355 South Colorado Boulevard

Suite 306

Denver, CO 80222

Description: The purpose of this contract is to provide technical analysis and consultation to CMS and its

components on home health related projects using the Outcome and Assessment Information Set (OASIS) and/or the Outcome Based Quality Improvement (OBQI) technique of quality improvement. The objective is to assist CMS to provide information that can be used to improve home health quality of care and also to design and implement a data analysis system to provide outcome data used for the public reporting of home health outcomes. Home health outcome information is derived from the analysis of data obtained from the collection and reporting by home health agencies of patient assessment information using OASIS.

Status: The public reporting data support system was completed in January 2003 to provide data for the Home Health Compare Web site. The contract was modified to provide continued support for the CMS public reporting effort, to provide additional technical and consultative support for the maintenance of the OASIS national reporting system and data repository and training in the collection of OASIS data, and to develop a Web-based training program for OBQI.

Development and Validation of MDS 3.0

Project No: 500-00-0027/02
Project Officer: Robert Connolly

Period: April, 2003 to December, 2006

Funding: \$2,919,000

Principal

Investigator: Debra Saliba **Award:** Task Order

Awardee: RAND Corporation

1700 Main Street PO Box 2138

Santa Monica, CA 90407-2138

Description: The purpose of this procurement is to refine and validate Version 3.0 of the MDS. The goal of the refinement is to produce a valid instrument that reduces user burden, represents the best "fit" for users (e.g., is more intuitive to the user); includes better use of standard assessment scales, use of common language from health information, and HIPAA standards; assesses resident quality of life; and where possible, is more resident centered.

Over the past year, CMS has convened a number of clinical meetings with industry experts to identify existing scales, indices, and measurement tools that are relevant to the nursing home setting. CMS has also identified a set of areas of priority within the MDS tool for further refinement. Information obtained by the clinical meetings will be shared with the offeror to help create a revised MDS tool.

Guidelines for each item must be developed that clarify the intent, definition, and process for collecting



and coding for each data item. This material must be suitable for software with wizards (or other online help features) and other intuitive data accumulation methods. Providers and stakeholders must be involved throughout the refinement and validation process. Crosswalks shall be developed that walk data items from 3.0 to 2.0 and from 2.0 to 3.0. In addition, for each data item considered for the MDS 3.0, the specific uses of the element must be identified (RUG item, quality measure. quality indicator, resident assessment protocols [RAP], etc.) as well as specifying implications of any revised item to the RAPs, the Prospective Payment Systems (PPS), and State-specific case mix systems. Special attention should also be paid to how the instrument can be modified to suit a quarterly assessment form and how the final instrument fits with the Medicare Payment Assessment Form (MPAF).

Payment items considered for revision cannot be changed unless a direct crosswalk between the revised item and the old payment item is available and must be validated in the field testing of the instrument. The offeror will take this information into consideration when redesigning the tool.

The offeror will also be responsible for developing a decision tree format within the instrument so that certain assessment items that do not apply to specific resident populations, for example, the pediatrics population, can be avoided while other items that are pertinent to that resident are retained for assessment. The goal is to create an instrument that is fluid and can adapt to various resident populations without being redundant or burdensome to facilities specializing in specific populations.

The offeror has proposed to CMS a selection of technical experts (i.e., providers, stakeholders, developers) to provide consultation to help inform the revision process and help the offeror sort through the feedback, tools, measures, and information shared with CMS by various interest groups and stakeholders. This consultation must include MDS designers, MDS experts, MDS users, and trainers to assure that the instrument builds on past knowledge and also is practical and user friendly. The offeror has also recommended to CMS the best consultative model: individual input from consultants, panels of experts working together on sections of the instrument or one formal technical expert panel (TEP). The offeror will be responsible for recommending MDS experts and, after input from the CMS project officer, will recruit MDS 3.0 technical experts and convene the individual and group meetings to inform the revision process.

The offeror will be required to convene and attend town hall meetings at CMS to seek feedback from various stakeholders on the current strengths as well as limitations of the MDS instrument and where revisions are critical in designing the MDS 3.0. This town hall meeting will be open to all interested parties and the feedback received must be taken into consideration and presented to the TEP.

Once a revised version has been created, the offeror will be responsible for conducting both an alpha and a natural field test validation of the instrument in multiple States and nursing home facilities, taking into consideration the utility of the measures, burden on providers, validity of the information collected relative to the information collected using the old instrument, and time required to complete the instrument relative to time burden for the 2.0.

CMS has established an agreement with the Department of Veterans Affairs (VA) to conduct the alpha test and natural field test of the instrument in a sample of their long-term care facilities. Nursing homes outside the VA system will also be recruited to ensure identification of a cross-sectional representation of providers. Representation from urban and rural, hospital-based and freestanding, chain and non-affiliated homes is expected. In addition, a subset of the homes specializing in the treatment of specific populations such as post-acute care, non-elderly adults (e.g., 18- to 65-year-olds), hospice patients, and Alzheimer's units must be identified in the validation sample.

This task will include recruiting facilities, providing assistance in helping them learn how to use the new instrument, coordinating feedback, and incorporating this feedback into a finalized tool.

Finally, the offeror will be responsible for developing and delivering training material that can be used by CMS to allow a seamless transition from MDS 2.0 to MDS 3.0. This may include video, documents, written manual instructions, and answers to potential frequently asked questions.

In designing the analytic plan and implementing the validation study, it is recommended that the contractor work with an organization knowledgeable about the MDS instrument, its history, and current uses. Further, it is recommended that the contractor work with an organization experienced in the provision of clinical consultation services, particularly in the long-term care setting. Under a previous study where a national validation study was required, the contractor worked with the State Quality Improvement Organizations to recruit nurses within each State to conduct the onsite validation and information collection. This approach was particularly effective in minimizing travel expenditures and expediting the onsite data collection. CMS recognizes that this is only one approach and is just discussed as one possible option in conducting the validation. Other options are also welcome but should be described in detail as part of the work plan.



Status: On April 23, 2003, a competitive RADSTO award was made to RAND under the leadership of Deb Saliba, M.D. (from RAND and UCLA) and Joan Buchanan (from Harvard University Medical School). In April 2004, a contract modification was made to RAND to extend the period of performance through December 31, 2006 to expand the number of States and size of the Natural MDS 3.0 Validation Sample. ■

Evaluation of the Use of Bedside Technology To Improve Quality of Care in Nursing Facilities

Project No: 500-00-0024/10
Project Officer: Renee Mentnech

Period: January, 2003 to January, 2005

Funding: \$820,388

Principal

Investigator: Leslie Greenwald Award: Task Order

Awardee: Research Triangle Institute (NC)

3040 Cornwallis Road

PO Box 12194

Research Triangle Park, NC

27709-2194

Description: CMS has awarded a contract to Research Triangle Institute, the University of Missouri Sinclair School of Nursing, and OneTouch Technologies to evaluate the use of hand-held technology in nursing homes. This project will examine the use of bedside technology to collect daily measures of resident care and outcomes in nursing facilities (NFs). The application of this new technology could be useful for improving the efficiency and effectiveness of care in these facilities.

The specific objectives of the project include evaluating whether—

- 1. The use of bedside data collection with portable computer devices, automated processes, and electronic medical records technology improves collection of daily measures of resident care in NFs
- 2. The use of this technology improves outcomes of care in NFs
- 3. Patient outcomes are enhanced by coupling the use of bedside technology with on-site clinical consultation by expert nurses.

Status: Recruitment of nursing homes and data collection are ongoing. ■

Shared Integrated Management Information System

Project No: 18-P-91723/05-02 Project Officer: Kathy Headen

Period: August, 2003 to July, 2004

Funding: \$347,725

Principal

Investigator:

Bruce Johnson

Award: Grant

Awardee: Illinois Primary Health Care

Association

225 South College Street, Suite 200

Springfield, IL 62704-1815

Description: The Illinois Primary Health Care Association is designing and will maintain a single, shared integrated management information system for all community health centers in Illinois. The project will consist of three phases, which they anticipate will take approximately 5 years to complete. The system will store information on patient scheduling, billing, accounts receivable, and patient outcomes tracking. The CMS funding is an addition to a grant from the Health Resources and Services Administration and other private entities.

Status: The first phase of the grant included software development and refinement, as well as connectivity of seven health care entities, including six Section 330 grantees and one provider of care to low-income women and children in Chicago. In phase II, a central server, a Wide Area Network infrastructure, and a mobile training center have been established. They have executed contracts with 14 community health centers. CMS FY 04 budget funds have been earmarked to continue the project after July 2004. ■

Construction of Analytic Files for Study of the Cardiac Rehabilitation Benefit Among Medicare Beneficiaries

Project No: 500-02-0006/01 Project Officer: William Clark

Period: September, 2002 to March, 2003

Funding: \$39,997

Principal

Investigator: Celia H. Dahlman
Award: Task Order

Awardee: CHD Research Associates

5515 Twin Knolls Road #322

Columbia, MD 21045

Description: The purpose of this task order is to provide programming support for the development of



analytic files that will be used to determine whether use of cardiac rehabilitation has a health benefit on Medicare beneficiaries as evidenced by a reduction in adverse outcomes, including hospitalizations, use of home health or long-term health services, or death. The study requires longitudinal files based on a cohort of Medicare beneficiaries who were candidates for cardiac rehabilitation from January 1995 through December 1996. All medical treatment received by this cohort will then be followed up for a period of up to 5 years subsequent to entry into the cohort.

Status: The project has been completed.

Improving Medication Safety in Outpatients Through Improved Packaging

Project No: 18-C-91678/05 Project Officer: Dennis Nugent

Period: September, 2001 to July, 2004

Funding: \$691,000

Principal

Investigator: Philip Schneider

Award: Cooperative Agreement

Awardee: Ohio State University Research

Foundation 1960 Kenny Road Columbus, OH 43210

Description: The purpose of this study is to determine if compliance packaging can increase adherence to a prescribed medication regimen and, concomitantly, improve treatment outcomes for elderly individuals who have a chronic disease. It was developed to reduce the frequency of drug errors by patients whose compliance with prescription instructions is critical. The project focuses on the impact of a packaging/distribution system and consumer education. Compliance packaging used in the study is a blister package with each dose of the medication identified by day of the week. Information regarding proper use and dosage is printed on the package. In order to participate in the project, an individual must have a diagnosis of hypertension and have a new or existing prescription for lisinopril. Hypertension was selected because it is a condition in which drug therapy plays a significant role in treatment outcome. Participants are randomly assigned to a study or comparison group. The study group's medication is distributed in "unit of use" packaging with special instructions; the control group receives standard prescription containers with the usual labeling. Compliance, treatment outcomes, and medical utilization of the two groups are being compared. Compliance is measured by interview, pill counts, refill regularity,

and blood pressure. Morbidity (angina, myocardial infarction, stroke, and renal impairment) and mortality rates are also quantified. In addition, medical service utilization is assessed by tabulating emergency room visits and hospitalizations. Each participant is followed for a period of 12 months.

Status: Preliminary results indicate some emerging differences between the study and comparison groups.

Northern New England Vascular Surgery Quality Improvement Initiative

Project No: 18-C-91674/01-02
Project Officer: Jackie Kennedy-Sullivan
Period: September, 2001 to

September, 2004

Funding: \$650,000

Principal

Investigator: Jack Cronenwett

Award: Cooperative Agreement

Awardee: Dartmouth University

HB 7850, 500 East Borwell Research Building Dartmouth Hitchcock Medical Center Hanover, NH 03756

Description: The Vascular Study Group of Northern New England (VSG-NNE) is a voluntary, cooperative group of clinicians, hospital administrators, and research personnel organized to improve the care of patients with vascular disease. By collecting and exchanging information, the group strives to improve the quality, safety, effectiveness, and cost of caring for patients with vascular disease in Maine, New Hampshire, and Vermont.

Status: A cooperative clinical data registry was developed among the nine major hospitals in NNE that perform 80 percent of all vascular surgery in the region. Data including indications, comorbidities, operative details, and outcomes will be collected for carotid endarterectomy, abdominal aortic aneurysm repair, and lower extremity bypass surgery.

The developed shared data registry prospectively collects data on vascular procedures. Data include indications, comorbidities, selected procedural details, and short-term outcomes and analyze patterns of care and outcomes of hospitals and surgeons. The variations in procedure rates and risk-adjusted outcomes will be added to account for the differences in case mix to improve outcomes and reduce geographic variation in procedure rates by using benchmarking and visits by clinical teams from each



center for comparative process analysis and continuous quality improvement. ■

Survey of Renal Dialysis Centers

Project No: 500-00-0028/01
Project Officer: Mary Stojak

Period: September, 2002 to February, 2003

Funding: \$145,844

Principal

Investigator: Trina Pifer **Award:** Task Order

Awardee: University Renal Research and

Education Association 315 West Huron, Suite 260 Ann Arbor, MI 48103

Description: This is a sole source. The purpose of the task order is to measure the amount and quality of nutrition therapy that is currently being provided to beneficiaries receiving dialysis.

Status: It has been completed. ■

The Impact of Alternative Low Vision Intervention on Quality

Project No: 18-P-91372/03
Project Officer: Joel Greer

Period: August, 2001 to August, 2004

Funding: \$1,000,000

Principal

Investigator: |.Vernon Odom

Award: Grant

Awardee: West Virginia Research

Corporation

West Virginia University

PO Box 6845

Morgantown, WV 26506-6845

Description: The General Provisions of the FY 2001 Appropriations legislation mandated an award "... to the West Virginia University School of Medicine's Eye Center to test interventions and improve the quality of life for individuals with low vision, with a particular focus on the elderly." The West Virginia University Research Corporation (WVURC) created and operates a regional center for vision rehabilitation services, the Appalachian Center for Visual Rehabilitation. The center serves the low vision needs of rural communities in West Virginia. WVURC collected data and performed an evaluation showing the effectiveness of its programs. It held a 2-day conference in the spring of 2003 to disseminate the lessons learned from the

project to other rural areas across the country. No final report is expected.

Status: The project ended 8/5/2003. ■

Assessment of State Database Capacity and Development of Prototype Performance Monitoring System

Project No: 18-C-91507/00 Project Officer: Joseph Razes

Period: September, 2001 to March, 2003

Funding: \$296,037

Principal

Investigator: Pamela Hanes

Award: Cooperative Agreement
Awardee: Oregon Health and Science

University

3181 SW Sam Jackson Park Road

DB669

Portland, OR 97201-3098

Description: This project collects, analyzes, and interprets data regarding States' Medicaid health systems development activities for individuals with disabilities and will develop a performance monitoring tool. This tool would be used by States in evaluating the success of their buy-in programs. Recent legislation has offered States unprecedented opportunities to use Medicaid as a vehicle for supporting the competitive employment of people with disabilities. The Balanced Budget Act of 1997 and the Ticket to Work and Work Incentives Improvement Act of 1999 have permitted States to implement a Medicaid buy-in that extends Medicaid coverage to working people with disabilities (who, because of earnings, would not otherwise qualify for Medicaid coverage under other statutory provisions). The new Medicaid buy-in offers new incentives to people with disabilities to work and increase earnings without risking the potential loss of health care coverage. The goal of this project is to lay the groundwork for-

- 1. Development of a national database that will integrate relevant Medicaid buy-in administrative data sets for future analysis
- 2. Identification and reporting of performance measures and benchmarks for use in evaluating the effectiveness of Medicaid buy-in programs

The rules and guidelines for implementing a State buy-in program are complex. While States have a tremendous amount of flexibility in how they design a Medicaid buy-in program, they also spend much time examining issues of health care access and barriers to employment for people with disabilities. The data and design



characteristics considered in their planning process ultimately influence the program that is developed and possible outcomes. The options available to States coupled with the array of rules to be followed can be confusing. Realizing the technical nature of the Medicaid buy-in programs and the fact that State staff often do not have the expertise, we have encouraged the development of two technical assistance partnerships. The primary purpose of these partnerships is to exchange information and ideas that will encourage States to take advantage of the Medicaid buy-in opportunities. As more States implement Medicaid buy-in programs nationally, increased technical assistance is needed. Part of this is help with data collection and development of analytical tools to assess the results and impact of the Medicaid buy-in.

Status: This project has ended.

QUALITY ASSURANCE AND QUALITY IMPROVEMENT IN HOME AND COMMUNITY-**BASED SERVICES**

The Quality Assurance and Quality Improvement in Home and Community-Based Services Grants, part of the Real Choice Systems Change Grants for Community Living, will assist States to (1) fulfill their commitment to ensuring the health and welfare of individuals who participate in the States' home and communitybased waivers under § 1915(c) of the Social Security Act, (2) develop effective and systematic methods to meet statutory and CMS requirements by the use of ongoing quality improvement strategies, and (3) develop improved methods that enlist the individual and community members in active roles in the quality assurance and quality improvement systems.

Status: This project is in its start-up phase.

Quality Assurance and Quality Improvement in Home and Community-Based Services

11-P-92009/09-01 **Project No: Project Officer:** Adrienne Delozier Period: September, 2003 to

September, 2006

\$499,844 **Funding:**

Principal

Investigator: Julie Jackson Award: Grant

Awardee: State of California Department

> of Development Services 1600 Ninth Street Room 340 MS 3-24 Sacramento, CA 95814

Quality Assurance and Quality Improvement in **Home and Community-Based Services**

11-P-92092/08-01 **Project No: Project Officer:** Maria Reed Period: September, 2003 to

September, 2006

\$499,851 **Funding:**

Principal

Investigator: Kerry O. Stern

Award: Grant

Awardee: Colorado Department of Human

Services

Division for Developmental

Disabilities

3824 West Princeton Circle

Denver, CO 80236

Quality Assurance and Quality Improvement in Home and Community-Based Services

Project No: 11-P-92080/01-01 **Project Officer:** Mark Reed **Period:** September, 2003 to

September, 2006

\$499,000 **Funding:**

Principal

Investigator: Elizabeth McArthur

Award: Grant

Awardee: Connecticut Department of

Mental Retardation 460 Capitol Avenue Hartford, CT 06016



Quality Assurance and Quality Improvement in Home and Community-Based Services

Project No: 11-P-92048/03-01
Project Officer: Maria Reed
September, 2003 to September, 2006

\$351,702

Funding: Principal

Investigator: Joseph B. Keyes

Award: Grant

Awardee: Delaware Health and

Social Services

Division Development Disabilities

Services

Jesse Cooper Building, Box 637

Dover, DE 19903

Quality Assurance and Quality Improvement in Home and Community-Based Services

Project No: 11-P-92024/01-01
Project Officer: Anita Yuskauskas
Period: September, 2003 to September, 2006

\$500,000

Funding: Principal

Investigator: Jim Moser Award: Grant

Awardee: Maine Department of Human

Services

Bureau of Medical Services State House Station #11 Kennebec County Augusta, ME 04333-0011

Quality Assurance and Quality Improvement in Home and Community-Based Services

Project No: 11-P-92111/04-01
Project Officer: Mark Reed
September, 2003 to September, 2006

Funding: \$475,000

Principal

Investigator: Patricia Clifford

Award: Grant

Awardee: Georgia Department of Human

Resources

Division of MHDDAD

Two Peachtree Street, NW, 22.224

Atlanta, GA 30303

Quality Assurance and Quality Improvement in Home and Community-Based Services

Project No: 11-P-92083/05-01
Project Officer: Anita Yuskauskas
Period: September, 2003 to
September, 2006

Funding: \$499,880

Principal

Investigator: Jolene Kohn Award: Grant

Awardee: Minnesota Department of

Human Services Medicaid Office 444 Lafayette Road St Paul, MN 55155

Quality Assurance and Quality Improvement in Home and Community-Based Services

Project No: 11-P-92095/05-01
Project Officer: Adrienne Delozier
September, 2003 to September, 2006

\$500,000

Funding: Principal

Investigator: Ellen McClimans

Award: Grant

Awardee: Indiana Family and Social

Services Administration 402 West Washington Street

Room W-451 PO Box 7083

Indianapolis, IN 46207-7083

Quality Assurance and Quality Improvement in Home and Community-Based Services

Project No: 11-P-92006/07-01 Project Officer: Mark Reed

Period: September, 2003 to September, 2006

Funding: \$500,000

Principal

Investigator: Vicki Keller Award: Grant

Awardee: Missouri Department of Health and

Senior Services/DSS&R 920 Wildwood Drive

PO Box 570

Jefferson City, MI 65102



Quality Assurance and Quality Improvement in Home and Community-Based Services

Project No: 11-P-92136/02-01
Project Officer: Adrienne Delozier
Period: September, 2003 to September, 2006

Funding: \$495,811

Principal

Investigator: Kathryn Kuhmerker

Award: Grant

Awardee: New York State Department

of Health

One Commerce Tower, Room 724

Albany, NY 12260

Quality Assurance and Quality Improvement in Home and Community-Based Services

Project No: 11-P-92122/00-01
Project Officer: Mark Reed
Period: September, 2003 to

September, 2006 \$455,113

Funding:

Principal

Investigator: DeAnna Hartwig

Award: Grant

Awardee: Oregon Department of Human

Services—Seniors and People with Disabilities 500 Summer Street, NE, E-02 Salem, OR 97301-1073

Quality Assurance and Quality Improvement in Home and Community-Based Services

Project No: 11-P-92078/04-01
Project Officer: Maria Reed
September, 2003 to September, 2006

Funding: \$475,100

Principal

Investigator: Steven E. Hairston

Award: Grant

Awardee: North Carolina DHHS/Division

of Mental Health DD/ Substance Abuse Services 2001 Mail Service Center Raleigh, NC 27699-2001

Quality Assurance and Quality Improvement in Home and Community-Based Services

Project No: 11-P-92120/03-01
Project Officer: Mark Reed
Period: September, 2003 to

September, 2006

Funding: \$498,650

Principal

Investigator: Gregory Howe

Award: Grant

Awardee: Pennsylvania Department of

Public Welfare

Commonwealth of Pennsylvania

Harrisburg, PA 17120

Quality Assurance and Quality Improvement in Home and Community-Based Services

Project No: 11-P-92057/05-01
Project Officer: Mark Reed
Period: September, 2003 to

September, 2006 \$499,740

Funding: Principal

Investigator: Donald Bashaw

Award: Grant

Awardee: Ohio Department of Mental

Retardation/Development Disability 35 East Chestnut Street, 5th Floor Columbia, OH 43215-2541

Quality Assurance and Quality Improvement in Home and Community-Based Services

Project No: 11-P-92050/04-01
Project Officer: Mark Reed
Period: September, 2003 t

eriod: September, 2003 to September, 2006

Funding: \$500,000

Principal

Investigator: Kathi K. Lacy
Award: Grant

Awardee: South Carolina Department of

Disabilities and Special Needs 3440 Harden Street Extension Richland County, SC 29203



Quality Assurance and Quality Improvement in Home and Community-Based Services

Project No: 11-P-92036/4-01
Project Officer: Anita Yuskauskas
Period: September, 2003 to September, 2006

Funding: \$452,636

Principal

Investigator: Tami Wilson Award: Grant

Awardee: Tennessee Department of Finance

and Administration

DMR, 500 Deaderick Street Andrew Jackson Building

15th Floor

Nashville, TN 37243

Quality Assurance and Quality Improvement in Home and Community-Based Services

Project No: 11-P92114/03-01
Project Officer: Mark Reed
Period: September, 2003 to

September, 2006

Funding: \$499,995

Principal

Investigator: Nancy Atkins

Award: Grant

Awardee: West Virginia DHHR/

Bureau of Medical Services/ Office of the Secretary Capitol Complex Building 3

Room 206

Charleston, WV 25305

Quality Assurance and Quality Improvement in Home and Community-Based Services

Project No: 11-P-92027/06-01
Project Officer: Maria Reed
September, 2003 to September, 2006

Funding: \$500,000

Principal

Investigator: Teresa Richard

Award: Grant

Awardee: Texas Department of Mental Health

and Mental Retardation 909 West 45th Street PO Box 12668 Austin,TX 78751

Quality Assurance and Quality Improvement in Home and Community-Based Services

\$500,000

Project No: 11-P-92085/005-01
Project Officer: Anita Yuskauskas
Period: September, 2003 to September, 2006

Funding: Principal

Investigator: Judith E. Frye **Award:** Grant

Awarde: Wisconsin DHFS/Division of

Disability and Elder Services One West Wilson Street

PO Box 7850

Madison, WI 53707-7850

Quality Assurance and Quality Improvement in Home and Community-Based Services

Project No: 11-P-92114/03-01
Project Officer: Mark Reed
Period: September, 2003 to

September, 2006

Funding: \$499,995

Principal

Investigator: Nancy Atkins Award: Grant

Awardee: West Virginia DHHR/

Bureau of Medical Services/ Office of the Secretary Capitol Complex Building 3

Room 206

Charleston, WV 25305

